

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Fernando Albericio Palomera et al.

Serial No.: 10/570,734

Group Art Unit: 1623

371 Date: Oct. 18, 2006

Examiner: tba

For: New Antitumoral Compounds

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☒ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in

**U.S. Patent 6,274,551: cited references A16 and A17 from Form PTO 1449b.**

4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or
  - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
  - ☒ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or

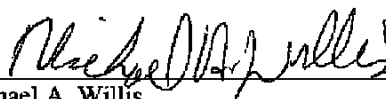
- ☐ 37 C.F.R. §1.97(b)(4) before the mailing date of a first office action after the filing of an RCE under §1.114.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.
- ☐ Charge the fee to Deposit Account No. 50-3732, Order No. 13566.105010.
7. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. the fee due under 37 C.F.R. §1.17(p) which is paid as set forth in paragraph 11 below.
8. ☐ This Information Disclosure Statement is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3) or §1.313(c)(1), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h);
- b. ☐ 37 C.F.R. §1.313(c)(2) or §1.313(c)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Request for Continued Examination (RCE) or a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h).
- c. ☐ The fee due under 37 C.F.R. §1.17(h) is paid as set forth in paragraph 11 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(e) more than three months prior to the filing of this Information Disclosure Statement.
10. ☐ This document is accompanied by ☐ a Search Report ☐ Communication which was cited in a corresponding ☐ PCT or ☐ Foreign counterpart application.
11. ☐ A check in the amount of \$            is enclosed in payment of the fees due under 37 C.F.R. §§1.17(h) and 1.17(p).
- ☐ Charge the fees due under 37 C.F.R. §§1.17(h) and 1.17(p) to Deposit Account No. 50-3732, Order No. 13566.105010.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 50-3732, Order No. 13566.105010.

Respectfully submitted,  
KING & SPALDING LLP

Dated: April 4, 2007

By: \_\_\_\_\_

  
Michael A. Willis  
Registration No. 53,913

Correspondence Address:

King & Spalding LLP  
1185 Avenue of the Americas  
New York, NY 10036  
212-556-2100 Telephone  
212-556-2222 Facsimile

## RELATED CASE STATEMENT

SERIAL NO.	371 DATE	ATTY. DOCKET NO.
10/570,734	Oct. 18, 2006	13566.105010
APPLICANT	GROUP ART UNIT / EXAMINER	
Fernando Albericio Palomera et al.	to be determined	

## PENDING U.S. PATENT APPLICATIONS

EXAM. INITIAL	PATENT APPLICATION SERIAL NUMBER	FILING DATE	NAME OF FIRST-NAMED APPLICANT		
	10/182,881	06-3-2003	Fernando Albericio et al.		
	11/587,177	01-02-07	Andres Francesch Solloso et al.		
	10/492,670	11-03-2004	Jose Jimeno		
	10/399,571	11-14-2003	Glynn Faircloth		
	10/642,006	08-14-2003	Paul Scheuer		
	10/546,758	10-10-2006	Miguel Angel Izquierdo Delso et al.		
	10/531,533	04-25-2006	Glynn Faircloth et al.		

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

## FORM PTO 1449a

## INFORMATION DISCLOSURE STATEMENT

Applicant (s):	Fernando Albericio Palomera et al.	Serial No.:	10/570,734
Filing Date:	October 18, 2006	Group Art Unit:	1623
Examiner:	to be determined	Confirmation:	7206

## U.S. PATENT DOCUMENTS

Examiner Initial	Patent No.	Issue Date	Name	Class	Subclass	Filing Date
	US 6,011,010	Jan. 4, 2000	Gravalos et al.			
	US 5,849,704	Dec. 15, 1998	Sorensen et al.			
	US 4,959,175	Sep. 25, 1990	Yatzidis			
	US 5,932,189	Aug. 3, 1999	Dean et al.			
	US 2004/0052764	Mar. 18, 2004	Hildinger et al.			
	US 2003/0157685	Aug. 21, 2003	Zervos			
	US 2004/0214755	Oct. 28, 2004	Albericio et al.			
	US 2004/0067895	Apr. 8, 2004	Faircloth et al.			
	US 2006/0234920	Oct. 19, 2006	Faircloth et al.			
	US 2005/0054555	Mar. 10, 2005	Jimeno et al.			

Examiner	Date Considered
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

**FORM PTO 1449b****INFORMATION DISLCOSURE STATEMENT**

Applicant (s):	Fernando Albericio Palomera et al.	Serial No.:	10/570,734
Filing Date:	October 18, 2006	Group Art Unit:	1623
Examiner:	to be determined	Confirmation:	7206

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Patent Number	Pub. Date	Country	Translation	
					YES	NO
	B1	WO 2005/103072	Nov. 3, 2005	WIPO		
	B2	WO 2002/36145	May 10, 2002	WIPO		
	B3	EP 0 838 221	Apr. 29, 1998	Europe		
	B4	WO 99/42125	Aug. 26, 1999	WIPO		
	B5	EP 0 610 078	Aug. 10, 1994	Europe		
	B6	WO 2004/075910	Sep. 10, 2004	WIPO		
Examiner				Date Considered		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

## FORM PTO 1449b

### INFORMATION DISCLOSURE STATEMENT

Applicant (s):	Fernando Albericio Palomera et al.	Serial No.:	10/570,734
Filing Date:	Oct. 18, 2006	Group Art Unit:	1623
Examiner:	to be determined	Confirmation:	7206

#### OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

<b>A1</b>	Vippagunta et al., "Crystalline Solids," Adv Drug Deliv Rev, vol. 48, iss. 1, pages 3-26, May 16, 2001
<b>A2</b>	Nuijen B et al., "Development of a lyophilized parenteral pharmaceutical formulation of the investigational polypeptide marine anticancer agent kahalalide F" Drug Development and Industrial Pharmacy, vol. 27, No. 8, pages 767-780, 2001.
<b>A3</b>	Faircloth G et al., "Preclinical development of kahalalide F, a new marine compound selected for clinical studies," Proceedings of the American Association for Cancer Research Annual, no. 41, March 2000 (2000-03), pages 600-601, XP001097542, 91 <sup>st</sup> Annual Meeting of the American Association for Cancer Research, San Francisco CA, USA; April 01-05, 2000, March, 2000 ISSN: 0197-016X
<b>A4</b>	Luber-Narod J et al., "Evaluation of the use of in vitro methodologies as tools for screening new compounds for potential in vivo toxicity." Toxicology In Vitro, vol. 15, no. 4-5, August 2001 (2001-08), pages 571-577, XP002225749, ISSN: 0887-2333, page 576, column 2, paragraph 2
<b>A5</b>	Brown Alan P et al., "Preclinical toxicity studies of kahalalide F, a new anticancer agent: single and multiple dosing regimens in the rat." Cancer Chemotherapy and Pharmacology. Germany Oct 2002, vol. 50, no. 4, October 2002 (2002-10), pages 333-340, XP002225750 ISSN: 0344-5704 abstract
<b>A6</b>	El Sayed, Khalid A. et al., "The Marine Environment: A Resource for Prototype Antimalarial Agents," Journal of Natural Toxins, Vol. 5, No. 2, pp. 261-285, 1996
<b>A7</b>	Garcia-Rocha, Mar et al., "The antitumoral compound Kahalalide F acts on cell lysosomes," Cancer Letters, vol. 99, no. 1, pp. 43-50, 1996
<b>A8</b>	Goetz, Gilles et al., "The Absolute Stereochemistry of Kahalalide F," Tetrahedron, vol. 55, pp. 7739-7746, 1999
<b>A9</b>	Goetz, Gilles et al., "Two Acyclic Kahalalides from the Sacoglossan Mollusk Elysia rufescens," Journal of Natural Products, vol. 60, no. 6, p. 562-567, 1997
<b>A10</b>	Hamann, Mark T. et al., "Kahalalide F: A Bioactive Depsipeptide from the Sacoglossan Mollusk Elysia rufescens and the Green Alga Bryopsis sp.," Journal of the American Chemical Society, vol. 115, no. 13, pp. 5825-5826, 1993

Examiner

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

# FORM PTO 1449b

## INFORMATION DISCLOSURE STATEMENT

Applicant (s):	Fernando Albericio Palomera et al.	Serial No.:	10/570,734
Filing Date:	Oct. 18, 2006	Group Art Unit:	1623
Examiner:	to be determined	Confirmation:	7206

### OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

A11	Hamann, Mark T. et al., "Kahalalides: Bioactive Peptides from a Marine Mollusk Elysia refuscens and Its Algal Diet Bryopsis sp.," The Journal of Organic Chemistry, vol. 63, no. 14, pp. 4856, 1998
A12	Horgen, F. David et al., "A New Depsipeptide from the Sacoglossan Mollusk Elysia ornate and the Green Alga Bryopsis Species," Journal of Natural Products, vol. 63, no. 1, pp. 152-154, 2000
A13	Kan, Yukiko et al., "Kahalalide K: A New Cyclic Depsipeptide from the Hawaiian Green Alga Bryopsis Species," Journal of Natural Products, vol. 62, no. 8, pp. 1169-1172, 1999
A14	Lopez-Macia, Angel et al., "Kahalalide B. Synthesis of a natural cyclodepsipeptide," Tetrahedron Letters, vol. 41, pp. 9765-9769, 2000
A15	Goodman & Gilman's, The Pharmacological Basis of Therapeutics, Ninth Edition, McGraw Hill, New York (1996), Section X, Chemotherapy of Neoplastic Diseases, pages 1225-1229.
A16	Hamann, Mark Todd, Ph.D., University of Hawaii (1992), "Biologically Active Constituents of Some Marine Invertebrates," UMI Dissertation Services, published October 1993.
A17	Merck Manual, 11 <sup>th</sup> ed., pp. 456-459, 761-763, and 1368-1371; published 1969.
A18	Lee Y S et al., "A convergent liquid-phase synthesis of salmon calcitonin" Journal of Peptide Research, Munksgaard International Publishers, Copenhagen DK, vol. 54, no. 5, October 1999 (1999-10), pages 328-335, XP000849313 ISSN: 1397-002X, figure 1
A19	Bonnard Isabelle et al., "Stereochemistry of kahalalide F," Journal of Natural Products. Nov 2003, vol. 66, no. 11, November 2003 (2003-11), pages 1466-1470, XP002337530 ISSN: 0163-3864 abstract
A20	Gura, "Cancer Models-Systems for identifying new drugs are often faulty," Science, vol. 278, pages 1041-2, Nov. 7, 1997

Examiner

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.